K102767
p1/4

JUN - 3 2011

1. 510(k) Summary - Basic Information

1.1 Submitter

Submitter: Bionet Co., LTD

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Date Prepared: April 13, 2011

1.2 Device Name

Device Name: *CardioXP*
Common Name: Electrocardiograph
Classification Name: Electrocardiograph (870.2340, Class II)

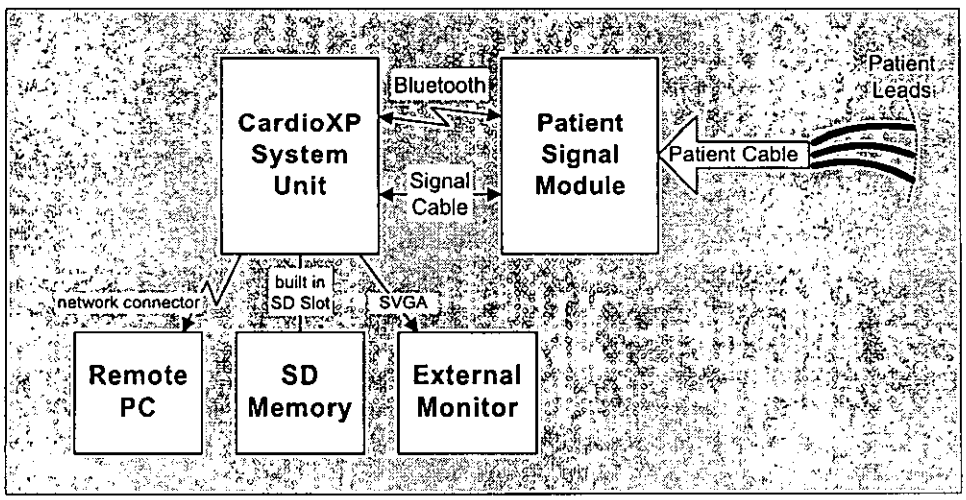
1.3 Identification of Legally Marketed Device

Substantial equivalence is claimed to the *Welch Allyn CP 200™ Electrocardiograph with Optional Spirometry* (K072449).

1.4 Device Description

CardioXP is an EKG monitoring system that provides standard EKG diagnostic functions. It offers enhanced usability, data analysis and data management. It consists of the several components depicted in Figure 1 that perform EKG monitoring, data analysis and data management functions.

Figure 1: CardioXP Block Diagram Depiction



1.5 Intended Use

CardioXP is intended for use as a diagnostic tool by trained operators in health facilities. It provides the following functions:

- Acquire ECG waveform data from up to twelve (12) leads through surface electrodes adhered to the patient's body.
- Input patient data.
- View, store and print captured data.
- Analyze captured data; display and print analysis results.
- Retain captured data and analysis results for up to 120 patients.
- Transfer retained data to a PC (via server IP) or directly to insertable SD RAM.

1.6 Comparison to Cleared Device

Table 1 compares the relevant features of *CardioXP* to the *Welch Allyn CP 200™ Electrocardiograph with Optional Spirometry.*

Table 1: Comparison of CardioXP to Welch Allyn CP 200

	Welch Allyn CP200	Bionet CardioXP
Operating Principle	electrocardiographs	same
Target Population	Adult and pediatric patients	same
ECG Acquisition	Simultaneous 12 leads resting ECG data cables plug into front end harness which then connects directly to CP200 unit.	Simultaneous 12 leads resting ECG connects to Patient Signal Module. CardioXP System Unit receives data from Patient Signal Module using either (1) direct cable connection or (2) Bluetooth communication.
Sampling Rate	1000 samples/sec/channel	500 samples/sec/channel
Filters	• 0.5 Hz high-performance baseline filter • 35Hz muscle-tremor filter • AC interference filter	• AC (50/60 Hz, -20dB or better), • Muscle (25~35Hz, -3dB or better), • Base line drift (0.1Hz, -3dB or better), • Low pass filter(off, 40Hz, 100Hz, 150Hz)
Display Functions	• View and adjust ECG waveforms. • Spirometry option provides for view patients' information.	• View and adjust ECG waveforms. • Does not have spirometry option.
Display Type	built in color LCD	same
User Input	• Integrated alphanumeric keyboard • dedicated function keys	touch screen and rotary push-knob
data Storage	• Storage for up to 50 ECG and 50 Spirometry records • Additional storage available using built in SD RAM slot	• Storage for up to 120 ECG • Does not have spirometry option. • Additional storage available using built in SD RAM slot
Weight	11.6 lb	Approx. 4 kg (8.8 lb)
Dimensions	16.2 x 15.6 x 6.2 in	300 x 299 x 123mm (11.8 x 11.8 x 4.8 in)
Power Source	AC power supply (100 ~ 240 VAC, 50/60Hz, 65 VA max) or battery power.	AC power supply (95 ~ 240 VAC, 50/60Hz, 60 VA max) or battery power.
Battery	• 4 hours of normal use or print 100 ECG pages. • Battery recharge to full capacity in 12 hours.	• 3 hours of normal use or print 300 ECG pages. • Battery recharge to full capacity in 8 hours.
Printer	Thermal printer (internal)	same

	Welch Allyn CP200	Bionet CardioXP
Sterility	Wipe exterior of patient cable and electrocardiograph with damp cloth using mild detergent diluted in water. Disinfect patient cable using damp cloth of chemical disinfectants containing one of the following: • ethanol (70% - 80%) • propanol (70% - 80%) • aldehydes (2% - 4%)	same
Safety	Recognized and applicable standards: • EC11 (AAMI/ANSI) • UL60601-1 • IEC 60601-1-1 • IEC 60601-1-2 • IEC 60601-1-4 • IEC 60601-2-25 • IEC 60601-2-51	Recognized and applicable standards: • EC11 (AAMI/ANSI) • IEC 60601-1-1 • IEC 60601-1-2 • IEC 60601-1-4 • IEC 60601-1-6 • IEC 60601-1-8 • IEC 60601-2-25 • ISO 10993-1:2003 • ISO 14971:2007 • ETSI EN 301 489 • ETSI EN 300 328 • EN 60950-1
Network Connection	Wireless	Hardwired Ethernet
Indication for Use	The electrocardiograph is one of the tools that clinicians use to evaluate, diagnose, and monitor patient cardiac function. The 12-lead ECG interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information. The optional spirometry module is indicated for use in clinical situations to assess a patient's pulmonary health status and evaluated symptoms, signs, or abnormal laboratory test results.	The CardioXP electrocardiograph is one of the tools that clinicians can use to evaluate and diagnose patient cardiac function. The 12-lead ECG interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information.

1.6.1 Differences between CardioXP and CP200

The meaningful difference between *CardioXP* and CP200 is the method of ECG data acquisition.

- In the case of CP200, patient leads plug into a front end harness, which then connects to a COM port on the CP200 system unit.
- In the case of *CardioXP*, patient leads plug into a front end harness, which plugs into a special adapter on the Patient Signal Module. The Patient Signal Module passes the raw ECG data to the *CardioXP* system unit as if the data had come directly from the patient leads.[1] The data transfer to the system unit can be accomplished by direct cable connection or wireless (Bluetooth) data transfer.
- While CP200 includes an optional spirometry option, the current *CardioXP* offering does not provide a spirometry option

[1] The Patient Signal Module also provides basic single signal display functions.

2. Performance Information

Because *CardioXP* complies with the EC11 standard, assessment of performance data is not necessary to determine of Substantial Equivalence for this type of device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 3 2011

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c/o Mr. Marc Goodman
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Re: K102767
Trade/Device Name: CardioXP
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: May 12, 2011
Received: May 16, 2011

Dear Mr. Goodman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102767

Indications for Use Statement

510(k) Number (if known) K102767

Device Name CardioXP

Indications for Use The CardioXP electrocardiograph is one of the tools that clinicians can use to evaluate and diagnose patient cardiac function. The 12-lead ECG interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102767